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Food and Agricultural Import Regulations and Standards

MRL changes - Dichlormid, Fenamidone, Buprofezin, Amitraz and Etoxazole

2008

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Report Highlights:

On July 28, 2008, Government of Japan announced proposed changes to the MRLs for Dichlormid, Fenamidone, Buprofezin, Amitraz and Etoxazole. The comment period will close on August 11, 2008. After the domestic comment period closes, MHLW will then notify these proposed changes to the WTO/SPS committee.

Includes PSD Changes: No
Includes Trade Matrix: No
Trade Report
Tokyo [JA1]
[JA]

Summary

The Japanese Ministry of Health Labour and Welfare (MHLW) announced on June July 28, 2008, proposed changes to the MRLs for Dichlormid, Fenamidone, Buprofezin, Amitraz and Etoxazole. The period for sending comments on these changes ends August 11, 2008. If you have comments it is best to send directly to MHLW as soon as possible. However, MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date; this will constitute the final decision.

The comments can be either Japanese or English.

If you have comments, please send them directly to the Japanese Government at:

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Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Establishment of Maximum Residue Limits for the Pesticides and Veterinary Drug (Dichlormid, Fenamidone, Buprofezin, Amitraz and Etoxazole) in Food

Purpose and Background

The Ministry of Health, Labour and Welfare (MHLW) is going to develop the compositional specification for food.

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare is authorized to establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as just "agricultural chemicals") that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed unless such food complies with the established standards.

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system.

This time the MHLW has reviewed MRLs for some pesticides which had been provisionally established at the time of the introduction of the new system. Also, the MHLW has newly established draft MRLs for some food commodities.

This activity is targeted to 5 chemicals: Dichlormid, Fenamidone, Buprofezin, Amitraz and Etoxazole. Details are given below.

Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.

Outline of revision

Dichlormid (Herbicide safener): This chemical is not permitted for use in Japan. The MRL for the substance on corn was established at the introduction of the positive list, based on the U.S. tolerance. This time, the MHLW has decided to withdraw the MRL. This is because the U.S. tolerance is time-limited and will expire on December 31, 2008. In addition, countries other than Japan and the United States have no MRL for dichlormid on corn. The MRL, which currently appears in the Provisional MRLs List in Item 7, will be deleted. After the revision takes effect, the uniform limit (0.01 ppm) will be applied.

Fenamidone (Fungicide): This chemical is already permitted for use in Japan. A foreign business has filed an application with the MHLW for the establishment of MRLs for the chemical, based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan, published on 5 February 2004. In response to the application, the MHLW has newly established MRLs (draft) for some crops and has comprehensively reviewed the existing MRLs.

Buprofezin (Insecticide): This chemical is already permitted for use in Japan. The MHLW has reviewed MRLs which had been provisionally established at the time of the introduction of the new system. Also, the MHLW has newly established a MRL (draft) for the "aquatic animals" category.

Amitraz (Insecticide.Vermicide): This chemical is already permitted for use as an insecticide in Japan. MAFF has decided to approve some veterinary drug products whose effective ingredient is amitraz. In response to the MAFF's action, the MHLW has comprehensively reviewed the existing MRLs for this substance. For fat of cattle, pig, and animals falling into the category "other terrestrial mammals," draft MRLs were once proposed in the FSG meeting held on March 24. However, the proposed MRLs have been modified this time, based on EU standards. This is because underlying data used in setting the EU standards were provided from the European Union to the MHLW after the meeting.

Etoxazole (Insecticide.Acaricide): This chemical is already permitted for use as an insecticide in Japan. MAFF has decided to approve some veterinary drug products whose effective ingredient is etoxazole. In response to the MAFF's action, the MHLW has comprehensively reviewed the existing MRLs for this substance.

For draft MRLs, see Attachments 1-1 through 1-5.

The existing MRLs appear in either of the MRLs List (the Item 6, Section A "General Compositional Standards for Food," Part I "Food" in the Specifications and Standards for Food, Food Additives, Etc.) or Provisional MRLs List (Item 7, Section A), according to food commodities. These MRLs have been modified as necessary. Finalized MRLs for these chemicals will be placed on the MRLs List in Item 6, and the MRLs currently placed in Item 7 will be deleted.

Note:

The uniform limit (0.01 ppm) will be applied to commodities for which draft MRLs are not given. Some limits in the column, "MRL (draft)," remain unchanged from the current MRLs.

1. "Other cereal grains" refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat.
2. "Beans (dry)" includes butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya, and white beans.
3. "Other legumes/pulses" refers to all legumes/pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry), and spices.
4. "Other potatoes" refers to all potatoes, except potato, taro, sweet potato, yam, and konjac.
5. "Other cruciferous vegetables" refers to all cruciferous vegetables, except Japanese radish roots and leaves (including radish), turnip roots and leaves, horseradish, watercress, Chinese cabbage, cabbage, brussels sprouts, kale, komatsuna (Japanese mustard spinach), kyona, qing-geng-cai, cauliflower, broccoli, and herbs.
6. "Other composite vegetables" refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, shungiku, lettuce (including cos lettuce and leaf lettuce), and herbs.
7. "Other liliaceous vegetables" refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, nira, asparagus, multiplying onion, and herbs.
8. "Other umbelliferous vegetables" refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, mitsuba, spices, and herbs.
9. "Other solanaceous vegetables" refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper), and egg plant.
10. "Other cucurbitaceous vegetables" refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and makuwauri melon.
11. "Other mushrooms" refers to all mushrooms, except button mushroom, and shiitake mushroom.
12. "Other vegetables" refers to all vegetables, except potatoes, sugar beet, sugarcane, cruciferous vegetables, composite vegetables, liliaceous vegetables, umbelliferous vegetables, solanaceous vegetables, cucurbitaceous vegetables, spinach, bamboo shoots, okra, ginger, peas (with pods, immature), kidney beans (with pods, immature), green soybeans, mushrooms, spices, and herbs.
13. "Other citrus fruits" refers to all citrus fruits, except unshu orange (pulp), citrus natsudaikai (pulp), citrus natsudaikai (peel), citrus natsudaikai (whole), lemon, orange (including navel orange), grapefruit, lime, and spices.
14. "Other berries" refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.

15. "Other fruits" refers to all fruits, except citrus fruits, apple, Japanese pear, pear, quince, loquat, peach, nectarine, apricot, Japanese plum (including prune), mume plum, cherry, berries, grape, Japanese persimmon, banana, kiwifruit, papaya, avocado, pineapple, guava, mango, passion fruit, date and spices.

16. "Other oil seeds" refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.

17. "Other nuts" refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.

18. "Other spices" refers to all spices, except horseradish, wasabi (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), yuzu (Chinese citron) peels and sesame seeds.

19. "Other herbs" refers to all herbs, except watercress, nira, parsley stems and leaves, celery stems and leaves.

20. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.

21. "Other poultry" refers to all poultry, except chicken.

Attachment 1-1

Dichloromid (Herbicide safener)		
Commodity	MRL (draft) ppm	Current MRL ppm
Corn (maize)		0.05

Attachment. 1-2

Fenamidone(Fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Potato	0.02	0.02
Taro	0.02	0.02
Sweet potato	0.02	0.02
Yam	0.02	0.02
Other potatoes ⁴	0.02	0.02
Chinese cabbage	0.5	0.5
Cabbage	5.0	
Brussels sprouts	5.0	
Cauliflower	5.0	
Broccoli	5.0	
Other cruciferous vegetables ⁵	5.0	
Lettuce	20	20
Onion	0.2	0.2
Welsh (including leek)	1.5	1.5
Garlic	0.2	0.2
Nira		1.5
Other liliaceous vegetables ⁷	1.5	1.5
Carrot	0.15	
Tomato	1	1
Pimiento (sweet pepper)	1.0	
Egg plant	1.0	
Other solanaceous vegetables ⁹	3	
Cucumber	0.3	0.3
Pumpkin	0.15	0.15
Oriental pickling melon (vegetable)	0.15	0.15
Water melon	0.15	0.15
Melons	0.15	0.15
Makurauri melon	0.3	0.15
Other cucurbitaceous vegetables ¹⁰	0.15	0.15
Bamboo shoots		0.02
Ginger	0.02	0.02
Other vegetables ¹²	0.02	0.02
Strawberry	0.02	
Grape	3	3
Japanese persimmon		1
Sunflower seeds	0.02	
Cotton seeds	0.02	
Other spices ¹³	0.02	0.02
Other herbs ¹⁰	5.0	1.5

Fenamidone(Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Cattle, muscle	0.1	0.1
Sheep, muscle	0.1	0.1
Goat, muscle	0.1	0.1
Cattle, fat	0.1	0.1
Sheep, fat	0.1	0.1
Goat, fat	0.1	0.1
Cattle, liver	0.1	0.1
Sheep, liver	0.1	0.1
Goat, liver	0.1	0.1
Cattle, kidney	0.1	0.1
Sheep, kidney	0.1	0.1
Goat, kidney	0.1	0.1
Cattle, edible offal	0.1	0.1
Sheep, edible offal	0.1	0.1
Goat, edible offal	0.1	0.1
Milk	0.02	0.02
Tomato puree	2.0	2.0
Tomato paste	2.2	2.2

Attachment. 1-3

Buprofezin(Insecticide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.5	0.5
Wheat	0.3	0.3
Corn (maize)		0.5
Lettace	13	10
Other composite vegetables ⁵	3	5
Tomato	1	1
Pimiento (sweet pepper)	0.5	0.5
Egg plant	1	1
Other solanaceous vegetables ⁹	0.5	1
Cucumber	1	1
Pumpkin	0.5	1
Oriental pickling melon (vegetable)	0.5	1
Water melon	0.5	1
Melons	0.5	1
Makuwauri melon	0.5	1
Other cucurbitaceous vegetables ¹⁰	0.5	1
Okra		0.5
Peas, immature (with pods)	0.02	0.02
Button mushroom		0.5
Shiitake mushroom		0.5
Other mushrooms ¹¹		0.5
Other vegetables ¹²		5
Unshu orange, pulp	0.3	0.3
Citrus natsudaikai, whole	0.3	2
Lemon	2.5	2
Orange	1	2
Grapefruit	2.5	2
Lime	2.5	2
Other citrus fruits ¹³	2.5	2
Apple	2	0.5
Japanese pear	2	2
Pear	4.0	2
Quince	4.0	0.5
Loquat	4.0	1
Peach	1	1
Nectarine	1.9	0.5
Apricot	0.7	1
Japanese plum	1.9	1
Mume plum	1.9	1
Cherry	1.9	1

Bupropion(Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Strawberry		1
Raspberry		1
Blackberry		1
Blueberry		1
Cranberry		1
Huckleberry		1
Other berries ^{1c}		1
Grape	1	1
Japanese persimmon	1	0.5
Banana	0.2	0.5
Kiwifruit	0.5	1
Papaya	0.9	0.5
Avocado	0.3	0.5
Pineapple		0.5
Guava	0.3	0.5
Mango	0.9	0.5
Passion fruit	2	0.5
Date		1
Other fruits ^{2c}	0.7	1
Cotton seeds	0.35	1
Ginkgo nut		0.1
Chestnut	0.02	0.1
Pecan		0.1
Almond	0.05	0.1
Walnut		0.1
Other nuts ^{1c}		0.1
Tea	20	20
Other spices ^{1c}	5	5
Other herbs ^{1c}	3	5
Cattle,muscle	0.05	0.05
Pig,muscle	0.05	0.05
Other terrestrial mammals ^{3b} ,muscle	0.05	0.05
Cattle,fat	0.05	0.05
Pig,fat	0.05	0.05
Other terrestrial mammals,fat	0.05	0.05
Cattle,liver	0.05	0.05
Pig,liver	0.05	0.05
Other terrestrial mammals,liver	0.05	0.05
Cattle,kidney	0.05	0.05
Pig,kidney	0.05	0.05
Other terrestrial mammals,kidney	0.05	0.05
Cattle,edible offal	0.05	0.05
Pig,edible offal	0.05	0.05
Other terrestrial mammals,edible offal	0.05	0.05
Milk	0.01	0.01
Fish and Shellfish	0.2	

Attachment: 1-4

Amitraz (Insecticide/Vermicide)

Commodity	MRL (draft) (ppm)	Current MRL (ppm)
Rice (brown rice)		0.02
Wheat		0.02
Barley		0.02
Rye		0.02
Corn (maize)		0.02
Buckwheat		0.02
Other cereal grains ¹		0.02
Soybeans, dry		0.05
Beans, dry ²		0.02
Peas		0.02
Broad beans		0.02
Peanuts, dry		0.05
Other legumes/pulses ³		0.02
Potato		0.05
Taro		0.05
Sweet potato		0.05
Yam		0.05
Konjac		0.05
Other potatoes ⁴		0.05
Sugar beet		0.05
Japanese radish, roots		0.05
Japanese radish, leaves		0.05
Turnip, roots		0.05
Turnip, leaves		0.05
Horseradish		0.05
Watercress		0.05
Chinese cabbage		0.05
Cabbage		0.05
Brussels sprouts		0.05
Kale		0.05
Komatsuna, Japanese mustard spinach		0.05
Kyona		0.05
Qing-geng-cai		0.05
Cauliflower		0.05
Broccoli		0.05
Other cruciferous vegetables ⁵		0.05
Bardock		0.05
Salsify		0.05
Artichoke		0.05
Chicory		0.05
Endive		0.05
Shungiku		0.05
Lettuce		0.05
Other composite vegetables ⁶		0.05

Amitraz¹ Continued:

Commodity	MRL (or)H: ppm	Current MRL: ppm
Onion		0.05
Welsh (including leek)		0.05
Garlic		0.05
Asra		0.05
Asparagus		0.05
Multiplying onion		0.05
Other liliaceous vegetables ⁵		0.05
Carrot		0.05
Parasip		0.05
Parsley		0.05
Celery		0.05
Mitsuba		0.05
Other umbelliferous vegetables ⁶		0.05
Tomato	0.9	0.5
Pimiento (sweet pepper)		0.05
Egg plant		0.5
Other solanaceous vegetables ⁷		0.05
Cucumber	0.9	0.5
Pumpkin		0.05
Oriental pickling melon (vegetable)		0.05
Water melon		0.2
Melons		0.05
Mokuwaun melon		0.2
Other cucurbitaceous vegetables ¹²		0.05
Spinach		0.05
Bamboo shoots		0.05
Okra		0.05
Ginger		0.05
Peas, immature (with pods)		0.05
Kidney beans, immature (with pods)		0.05
Green soybeans		0.05
Button mushroom		0.05
Shitake mushroom		0.05
Other mushrooms ¹¹		0.05
Other vegetables ¹⁰		0.5
Unshu orange, pulp	0.5	0.5
Citrus natsudaidai, whole	0.5	0.5
Lemon	0.5	0.5
Orange	0.9	0.5
Grapefruit	0.5	0.5
Lime	0.5	0.5
Other citrus fruits ¹³	0.9	0.5
Apple	0.9	0.5
Japanese pear	0.9	0.5
Pear	0.9	0.5
Quince	0.9	0.5
Loquat	0.9	0.5

Amitraz(Continued):

Commodity	MRL (draft) ppm	Current MRL ppm
Peach	0.9	0.5
Nectarine	0.9	0.2
Apricot	0.9	0.2
Japanese plum	0.9	0.2
Mume plum	0.9	0.3
Cherry	0.9	0.5
Strawberry		0.2
Raspberry		0.2
Blackberry		0.2
Blueberry		0.2
Cranberry		0.2
Huckleberry		0.2
Other berries ¹²		0.2
Grape		0.05
Japanese persimmon		0.05
Banana		0.05
Kiwifruit		0.05
Papaya		0.2
Avocado		0.2
Pineapple		0.05
Guava		0.2
Mango		0.2
Passion fruit		0.2
Date		0.2
Other fruits ¹⁵		0.2
Sunflower seeds		0.2
Sesame seeds		0.05
Safflower seeds		0.2
Cotton seeds	0.9	0.5
Rapeseeds		0.2
Other oil seeds ¹⁶		0.2
Ginkgo nut		0.2
Chestnut		0.05
Pecan		0.2
Almond		0.2
Walnut		0.2
Other nuts ¹⁷		0.2
Tea		0.1
Hop		40
Other spices ¹³	5	0.5
Other herbs ¹⁸		0.05

Amitraz(Continued):

Commodity	MRL (draft) ppm	Current MRL ppm
Cattle, muscle	0.09	0.05
Pig, muscle	0.09	0.05
Other terrestrial mammals ²⁰ , muscle	0.2	0.1
Cattle, fat	0.2	0.1
Pig, fat	0.4	0.1
Other terrestrial mammals, fat	0.2	0.4
Cattle, liver	0.4	0.2
Pig, liver	0.4	0.2
Other terrestrial mammals, liver	0.4	0.2
Cattle, kidney	0.4	0.2
Pig, kidney	0.4	0.2
Other terrestrial mammals, kidney	0.4	0.2
Cattle, edible offal	0.4	0.2
Pig, edible offal	0.4	0.2
Other terrestrial mammals, edible offal	0.4	0.2
Milk	0.02	0.01
Chicken, muscle		0.02
Other poultry ²¹ , muscle		0.02
Chicken, fat		0.01
Other poultry, fat		0.01
Chicken, liver		0.04
Other poultry, liver		0.04
Chicken, kidney		0.04
Other poultry, kidney		0.04
Chicken, edible offal		0.04
Other poultry, edible offal		0.04
Chicken, eggs		0.02
Other poultry, eggs		0.02
Honey	0.2	0.2
Cottonseed oil (except refined cottonseed oil and cottonseed salad oil that meet the Japanese Agricultural Standards (JAS) for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	0.09	0.05

Attachment 1-5

Etoxazole (Insecticide/Acaricide)

Commodity	MRL (tolerance) ppm	Current MRL ppm
Beans, dry ²	0.3	0.5
Peas		0.5
Broad beans		0.5
Peanuts, dry		0.5
Other legumes/pulses ³		0.5
Tomato		0.1
Egg plant	0.5	0.5
Cucumber	0.3	0.5
Pumpkin		0.5
Oriental pickling melon (vegetable)		0.5
Water melon	0.2	0.1
Melons	0.2	0.1
Mokuweuri melon	0.2	0.1
Other cucurbitaceous vegetables ¹⁵	0.2	0.5
Unshu orange, pulp	0.5	1
Citrus natsudaidai, whole	0.7	1
Lemon	0.7	1
Orange	0.7	1
Grapefruit	0.7	1
Lime	0.7	1
Other citrus fruits ¹⁶	0.7	1
Apple	0.5	2
Japanese pear	0.5	0.5
Pear	0.5	0.5
Quince	0.2	0.5
Loquat	0.2	0.1
Peach	0.05	0.1
Nectarine	0.5	0.5
Apricot	0.1	1
Japanese plum	0.5	1
Mume plum	0.1	1
Cherry	1	1
Strawberry	0.5	1
Raspberry		1
Blackberry		1
Blueberry		1
Cranberry		1
Huckleberry		1
Other berries ¹⁴		1
Grape	0.5	1
Japanese persimmon		0.5

Etoxazole (Continued):

Commodity	MRL (date) ppm	Current MRL ppm
Banana		0.5
Kiwi/fruit		0.1
Papaya		0.5
Avocado		0.5
Pineapple		0.5
Guava		0.5
Mango	0.3	0.5
Passion fruit		0.5
Date		1
Other fruits ¹⁶	0.5	1
Cotton seeds	0.2	0.1
Chestnut	0.01	0.01
Pecan	0.01	0.01
Almond	0.01	0.01
Walnut	0.01	0.01
Other nuts ¹⁷	0.01	0.01
Tea	10	15
Hop	15	15
Other spices ¹⁸	10	1
Cattle, muscle	0.05	0.01
Pig, muscle	0.01	0.01
Other terrestrial mammals ²⁰ , muscle	0.01	0.01
Cattle, fat	0.05	0.02
Pig, fat	0.02	0.02
Other terrestrial mammals, fat	0.02	0.02
Cattle, liver	0.05	0.01
Pig, liver	0.01	0.01
Other terrestrial mammals, liver	0.01	0.01
Cattle, kidney	0.05	0.01
Pig, kidney	0.01	0.01
Other terrestrial mammals, kidney	0.01	0.01
Cattle, edible offal	0.05	0.01
Pig, edible offal	0.01	0.01
Other terrestrial mammals, edible offal	0.01	0.01
Milk	0.01	0.01
Chicken, muscle	0.01	0.01
Other poultry ²¹ , muscle	0.01	0.01
Chicken, fat	0.02	0.02
Other poultry, fat	0.02	0.02
Chicken, liver	0.01	0.01
Other poultry, liver	0.01	0.01
Chicken, kidney	0.01	0.01
Other poultry, kidney	0.01	0.01
Chicken, edible offal	0.01	0.01
Other poultry, edible offal	0.01	0.01
Chicken, eggs	0.01	0.01
Other poultry, eggs	0.01	0.01